

Food and Drug Administration Rockville MD 20857

OCT | 2 1999

## NADA 132-338

Ms. Celia C. Castaneda Regulatory Compliance Specialist Shering-Plough Animal Health Corporation 1095 Morris Avenue Union, NJ 07083

Dear Ms. Castaneda:

We have become aware of promotional material entitled "Hands-off Therapy...GENTOCIN Topical Spray", detailer number SPAH-OTO- 39R2, NADA 132-338. We have reviewed this promotional item and find it to be violative.

This promotional piece is violative because it fails to provide a fair balance and lacks risk information as required by 21 CFR 202.1(e)(5)(ii). For example, the use of such phrases as "...one of the most potent anti-inflammatories..." triggers the need to present the risk information included in the approved label.

We ask that this promotional piece and similar promotional material being used or intended to be used in the future be immediately stopped. In addition, we rquest that you review your company policies to give due consideration and attention to promotional practices and ensure that your promotional materials comply with the requirements of FDA regulations.

Please inform us of your intentions within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours.

Vitolis Vengris, D.V.M., Ph.D. Marketed Product Scientific and Regulatory Review, Team 1,

HFV-214

Division of Surveillance Center for Veterinary Medicine